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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/553,639 | 03/09/2006 | Izumu Saito | Q90948 | 4651 |

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

| EXAMINER | |
|---|---|
| BURKHART, MICHAEL D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/10/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/553,639 | SAITO ET AL. | |
| | Examiner | Art Unit | |
| | Michael Burkhart | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *10, 11, 13-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/18/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/05;* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group I in the reply filed on 5/24/2010 is acknowledged.

Claims 10, 11 and 13-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/24/2010.

### *Information Disclosure Statement*

Certain references listed on the IDS dated 3/9/2006 have been lined through because they are duplicates found on the IDS dated 10/18/2005.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Danthinne et al (Gene Ther., 2000).

Danthinne et al teach the creation of a cosmid vector comprising an adenoviral genome with both right and left ITRs, an E1 deletion, and flanked by PacI/SwaI restriction sites which are not found in the adenoviral genome. See Fig. 1 and page 81, first column, first full ¶ to the

second column. The cosmid comprises an ampicillin resistance gene, an origin of replication (ori), a spacer, and a cos region between the two LTRs. Absent a limiting definition in the specification, the spacer sequence is arbitrarily chosen as a sequence between any of the above components, e.g. between the right LTR and the ampicillin gene. As such, the ampicillin gene and *ori* are located between the left LTR and the spacer in Figure 1. Certain combinations of the plasmids used to prepare the cosmid result in a BstBI site on either "side" of the adenoviral genome, i.e. at the ΔE3 site and the ΔE1 site when the Psp1406I site is used in construction of the expression cassette. The limitation in claim 7 that the restriction site is used to insert a foreign gene into an E1 deletion site is an intended use limitation. If a prior art structure is capable of performing the intended use as recited, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). (MPEP 2111.02). The SwaI site is used in the ultimate construction of the E1-deleted vectors in mammalian cells, hence, it is considered to meet this intended use limitation. Likewise, claim 12 is an intended use for the vector of claim 1, and, as Danthinne et al used the cosmid to construct adenoviral vectors, this limitation is considered to be taught by Danthinne et al.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danthinne et al (Gene Ther., 2000) as applied to claims 1-3, 5-8 and 12 above, and in further view of Danthinne (J. Virol. Meth., 1999, cited by applicants).

The teachings of Danthinne et al (2000) are as above and applied as before.

Danthinne et al (2000) do not teach the precise arrangement of the components as recited in claim 4.

Danthinne et al (1999) teaches a cosmid similar to that of Danthinne et al (2000), but in which the order of the ampicillin resistance gene, SV40 ori, spacer, and cos are as specified in claim 4, i.e. from the left LTR to the right LTR. See the cosmid at the bottom of Fig. 1

The claimed cosmid is essentially disclosed by Danthinne et al (2000) with the exception of the order of the cosmid components in relation to the adenoviral LTRs. The ordinary skilled artisan, seeking to prepare an adenoviral cosmid, would have been motivated to use the order of cosmid components as specified in Danthinne et al (1999) with the cosmids and methods of Danthinne et al (2000) because both references teach these components to be well known and essential cosmid components, and the order of arrangement in relation to adenoviral LTRs to be a matter of design choice when preparing the cosmids from plasmid components. It would have

been obvious for the skilled artisan to do this because of the known benefit of generating adenoviral cosmids for foreign gene expression as taught by both of the Danthinne references. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danthinne et al (Gene Ther., 2000) as applied to claims 1-3, 5-8 and 12 above, and in further view of Miyake et al (PNAS, 1996, cited by applicants.

The teachings of Danthinne et al (2000) are as above and applied as before.

Danthinne et al (2000) do not teach the use of a CAG or EF1-α promoter for use in the E1 deletion site. Danthinne et al do teach the use of other common promoters at this site for expression of, for example, β-gal or luciferase. See Figs. 2 and 4.

Miyake et al teach the generation of cosmid-based adenoviral vectors comprising an E1 deletion into which a foreign gene is inserted, see the abstract and Fig. 1. Miyake et al also teach the use of the CAG and EF-1α promoters in the same situations. See page 1323, first column.

The claimed cosmid is essentially disclosed by Danthinne et al (2000) with the exception of the use of the specific promoters recited in claim 9. The ordinary skilled artisan, seeking to express a foreign gene using an adenoviral cosmid system, would have been motivated to use either the CAG or EF-1α promoters as taught by Miyake et al with the vectors and methods of Danthinne et al (2000) because both references teach a promoter to be essential for foreign gene

expression, and that the CAG or EF-1α promoters are particularly suited to this purpose. It would have been obvious for the skilled artisan to do this because of the known benefit of generating adenoviral cosmids for foreign gene expression as taught by both Danthinne and Miyake et al references. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

### *Double Patenting*

Applicant is advised that should claim 5 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 6 merely recites an inherent property of the DNA sequence set forth in claim 5, i.e. that it is recognized by the enzymes listed in claim 6. In no way does claim 6 differ in scope than claim 5.

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633